DEARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

9/1807d

October 4, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: NYK-2002-2

Mr. Morris Grunhut
President
Flaum Appetizing, Inc. (M&M)
288 Scholes Street
Brooklyn, NY 11206

Dear Mr. Grunhut:

We inspected your seafood processing facility, located at 288 Scholes Street, Brooklyn, New York on September 4-14, 2001, and found that you have serious deviations from the Seafood HACCP regulations (Title 21, Code of Federal Regulations, Part 123 (21 CFR 123)). These deviations, cause your ready-to-eat pickled seafood products to be in violation of Section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through the links in FDA's home page at www.fda.gov.

The deviations included, but are not limited to, the following:

1. You must maintain sanitation control records, that at a minimum, document the monitoring and correction of sanitation conditions and practices during processing to comply with 21 CFR 123.11 (c). However, inspection revealed no records covering sanitation monitoring while manufacturing your ready-to-eat seafood products.

2. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6 (b). However, your firm did not maintain cooler temperature records for the finished product cold storage critical control point.

3. Your HACCP plan must identify each of the food safety hazards that are likely to occur to comply with 21 CFR 123.6 (c). However, your HACCP plan for fish species subject to the histamine hazard, such as Herring, did not include this hazard at the finished product cold storage critical control point.

We may take further action if you do not promptly correct these deviations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter and the inspectional observations (Form FDA 483) issued to and discussed with Solomon Benatar, Production Manager, at the conclusion of the inspection, may not list all the deviations at your facility. You are responsible for ensuring that your seafood processing facility operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Lillian C. Aveta, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issues in this letter, please contact Ms. Aveta at (718) 662-5576.

Sincerely,

Jerome G. Woyshner
District Director
New York District

Enclosure: Form FDA 483 dated September 4-14, 2001